

WHAT IS CLAIMED AS NEW AND DESIRED TO BE SECURED BY LETTER
PATENT OF UNITED STATES IS:

1. A process for preparing a phospholipid suspension,
comprising:

5 (1) contacting a lipid blend with a non-aqueous
solvent, whereby the lipid blend substantially dissolves in
the non-aqueous solvent; and,

(2) contacting the solution from step (1) with an
aqueous solution to form a lipid suspension.

10 2. A process according to Claim 1, wherein the non-
aqueous solvent is selected from propylene glycol, ethylene
glycol, and polyethylene glycol 300.

15 3. A process according to Claim 2, wherein the non-
aqueous solvent is propylene glycol.

4. A process according to Claim 2, wherein the lipid
blend, comprises:

20 (a) 1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylcholine;

(b) 1,2-dipalmitoyl-*sn*-glycero-3-phosphotidic, mono
sodium salt; and,

(c) *N*-(methoxypolyethylene glycol 5000 carbamoyl)-1,2-
dipalmitoyl-*sn*-glycero-3-phosphatidylethanolamine, mono
25 sodium salt.

5. A process according to Claim 2, wherein the non-
aqueous solvent is heated to a temperature of about 30 to
70°C prior to contacting with the lipid blend.

30 6. A process according to Claim 5, wherein the non-
aqueous solvent is heated to a temperature of about 50 to
55°C prior to contacting with the lipid blend.

35 7. A process according to Claim 2, wherein the ratio
of lipid blend to non-aqueous solvent is from about 5 mg of
lipid blend per mL of non-aqueous solvent to about 15 mg/mL.

8. A process according to Claim 7, wherein the ratio of lipid blend to non-aqueous solvent is about 10 mg/mL.

5 9. A process according to Claim 2, wherein in step (2), the aqueous solution is selected from water, saline, a saline/glycerin mixture, and a saline/glycerin/non-aqueous solvent mixture.

10 10. A process according to Claim 9, wherein the aqueous solution is a saline and glycerin mixture.

11. A process according to Claim 9, wherein the aqueous solution is a saline, glycerin, and propylene glycol mixture.

15 12. A process according to Claim 11, wherein 6.8 mg/mL of sodium chloride are present, 0.1 mL/mL of glycerin are present, 0.1 mL/mL of propylene glycol are present, and about 0.75 to 1.0 mg/mL of the lipid blend are present.

20 13. A process according to Claim 12, wherein 0.75 mg/mL of lipid blend are present.

25 14. A process according to Claim 12, wherein 1.0 mg/mL of lipid blend are present.

30 15. A process according to Claim 2, wherein in step (2), the aqueous solution is heated to a temperature of about 45 to 60°C prior to contacting with the solution from step (1).

35 16. A process according to Claim 15, wherein the aqueous solution is heated to a temperature of about 50 to 55°C prior to contacting with the solution from step (1).

17. A process according to Claim 1, wherein the process further comprises:

(3) heating the lipid suspension from step (2) to a temperature about equal to or above the highest gel to liquid crystalline phase transition temperature of the lipids present in the suspension.

5

18. A process according to Claim 17, wherein in step (3), the lipid suspension is heated to a temperature of at least about 67°C.

10

19. A process according to Claim 17, wherein the process further comprises:

(4) filtering the lipid suspension through a sterilizing filter.

15

20. A process according to Claim 19, wherein in step (4), the filtration is performed using two sterilizing filter cartridges.

20

21. A process according to Claim 20, wherein in step (4), the sterilizing filter cartridges are at a temperature of from about 70 to 80°C.

25

22. A process according to Claim 21, wherein in step (4), 0.2µm hydrophilic filters are used.

30

23. A process according to Claim 19, wherein the process further comprises:

(5) dispensing the filtered solution from step (4) into a vial.

35

24. A process according to Claim 23, wherein the process further comprises:

(6) exchanging the headspace gas of the vial from step (5) with a perfluorocarbon gas.

25. A process according to Claim 24, wherein the perfluorocarbon gas is perfluoropropane.

26. A process according to Claim 25, wherein exchange of headspace gas is performed using a lyophilizing chamber.

27. A process according to Claim 24, wherein the
5 process further comprises:

(7) sterilizing the vial from step (6).

28. A process according to Claim 27, wherein in step
(7), the vial is sterilized at about 126-130°C for 1 to 10
10 minutes.

29. A process for preparing a lipid blend, comprising:

(a) contacting at least two lipids with a first non-
aqueous solvent;

15 (b) concentrating the solution to a thick gel;

(c) contacting the thick gel with a second non-aqueous
solvent; and,

(d) collecting the resulting solids.

20 30. A process according to Claim 29, wherein in step
(a), the lipids are:

(i) 1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylcholine;

(ii) 1,2-dipalmitoyl-*sn*-glycero-3-phosphotidic, mono
sodium salt; and,

25 (iii) *N*-(methoxypolyethylene glycol 5000 carbamoyl)-
1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylethanolamine, mono
sodium salt.

31. A process according to Claim 30, wherein in step
30 (a), the first non-aqueous solvent is a mixture of methanol
and toluene.

32. A process according to Claim 30, wherein in step
(c), the second non-aqueous solvent is a methyl *t*-butyl
35 ether.

33. A process according to Claim 30, wherein in step (a), the solution is warmed to a temperature sufficient to complete dissolution of the lipids into the solvent.

5 34. A process according to Claim 33, wherein in step (a), the solution is warmed to about 25 to 75°C.

35. A process according to Claim 30, wherein in step (d), the solids collected are washed with methyl *t*-butyl
10 ether and dried *in vacuo*.

36. A phospholipid suspension, comprising: ~

(a) a lipid blend in an amount of about 0.75 - 1.0 mg/mL of suspension;

15 (b) sodium chloride in an amount of about 6.8 mg/mL of suspension;

(c) glycerin in an amount of about 0.1 mL/mL of suspension;

(d) propylene glycol in an amount of about 0.1 mL/mL of
20 suspension; and

(e) water;

wherein the suspension is prepared by the process, comprising:

(1) contacting a lipid blend with a non-aqueous
25 solvent, whereby the lipid blend substantially dissolves in the non-aqueous solvent;

(2) contacting the solution from step (1) with an aqueous solution to form a lipid suspension;

(3) heating the lipid suspension from step (2) to a
30 temperature about equal to or above the highest gel to liquid crystalline phase transition temperature of the lipids present in the suspension; and,

(4) filtering the lipid suspension through a sterilizing filter.

35

37. A phospholipid suspension according to Claim 36, wherein the lipid blend, comprises:

(a) 1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylcholine;

(b) 1,2-dipalmitoyl-*sn*-glycero-3-phosphotidic, mono sodium salt; and,

(c) *N*-(methoxypolyethylene glycol 5000 carbamoyl)-1,2-dipalmitoyl-*sn*-glycero-3-phosphatidylethanolamine, mono sodium salt.

38. A phospholipid suspension according to Claim 37, wherein the non-aqueous solvent is heated to a temperature of about 50 to 55°C prior to contacting with the lipid blend.

39. A phospholipid suspension according to Claim 37, wherein the ratio of lipid blend to non-aqueous solvent is about 10 mg/mL.

40. A phospholipid suspension according to Claim 37, wherein the aqueous solution is a saline, glycerin, and propylene glycol mixture.

41. A phospholipid suspension according to Claim 40, wherein 0.75 mg/mL of lipid blend are present.

42. A phospholipid suspension according to Claim 37, wherein the aqueous solution is heated to a temperature of about 50 to 55°C prior to contacting with the solution from step (1).

43. A phospholipid suspension according to Claim 37, wherein in step (3), the lipid suspension is heated to a temperature of at least about 67°C.

44. A phospholipid suspension according to Claim 43, wherein in step (4), two 0.2µm hydrophilic filters are used.